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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/827,272	04/20/2004	Zhaoxi Ke	CL001313-DIV	2775

25748 7590 10/02/2006

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EXAMINER	
RAO, MANJUNATH N	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 10/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/827,272	KE, ZHAOXI	
	Examiner	Art Unit	
	Manjunath N. Rao, Ph.D.	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 April 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-23* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

[1] Claims 1-23 are currently pending in the application.

Election/Restrictions

[2] Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I, Claims1-2, 20-21, drawn to an isolated peptides/polypeptides, classified in class 435, subclass183.

Group II, Claim 3, drawn to an antibody that specifically interacts the polypeptide, classified in class 530, subclass 387.9.

Group III, Claims 4-6, 8-11, 22-23, drawn to isolated nucleic acid sequence, vector comprising the same, a host cell comprising said vector and a method of making the polypeptide using said host cell, classified in class 435, subclass 69.1.

Group IV, Claim 7, drawn to transgenic non-human animal comprising the isolated polynucleotide, classified in class 800, subclass 8.

Group V, Claim 12, drawn to a method for detecting the presence of a polypeptide, using a compound the selectively detects said polypeptide, classified in class 435, subclass 4,

Group VI, Claim 13, drawn to a method for detecting the presence of a nucleic using a nucleic acid probe, classified in class 435, subclass 6,

Group VII, Claims 14-15, drawn to a method of identifying a compound which modulates the activity of the polypeptide, classified in class 435, subclass 4.

Group VIII, Claim 16, drawn to a method of identifying a compound which binds to the polypeptide, classified in class 435, subclass 4.

Group IX, Claim 17, drawn to a pharmaceutical composition comprising the agent that binds the polypeptide, classified in class 514, subclass 758.

Group X, Claim 18, drawn to a method of treating a kinase protein mediated disease using a pharmaceutically effective agent that binds the polypeptide, classified in class _____, subclass _____.

Group XI, Claim 19, drawn to a method of identifying a compound which modulates the expression of the polypeptide, classified in class 435, subclass 6.

[3] The inventions are distinct, each from the other because of the following reasons:

[4] The polypeptides of Group I, the antibodies of Group II, the nucleic acid sequences of Group III, the transgenic non-human animal of group IV, the binding agent of Group IX, are all patentably distinct products. These inventions are distinct from each other for the following reasons. Each of the polypeptides, antibodies, nucleic acids, the binding compound and the transgenic animal are composed of amino acids, and each of the polynucleotides, which are composed of purine and pyrimidine units,

are structurally distinct molecules; any relationship between the polypeptide, the nucleic acids, the antibodies and the transgenic animal is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. Furthermore, the information provided by the polynucleotide can be used to make a materially different polypeptide than that of group III. In addition, while a polypeptide of group III can made by methods using some, but not all, of the polynucleotides that fall within the scope of group III, it can also be recovered from a natural source using biochemical means. For instance, the polypeptide can be isolated using affinity chromatography. Also, the polypeptide can be made using purely synthetic means. For these reasons, the polypeptides, the nucleic acids, the antibodies, the transgenic animal and the binding agent are all patentably distinct.

Furthermore, searching the polypeptides of Group I, or the nucleic acids of group III or the antibody of group II, or the transgenic animal or the binding compound together would impose a serious search burden. In the instant case, the search of the polypeptide, the antibody, the polynucleotide, the transgenic animal or the binding compound are not coextensive. The inventions of these Groups have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the

polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive. The scope of polynucleotides as claimed extend beyond the polynucleotide that encodes the claimed polypeptides as explained above. As such, in addition to the distinctness of each of the above invention, it would be burdensome to search the inventions together.

[5] The polypeptides of Group I, the antibody of Group II and the method of groups V, VII, VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide can be independently used to generate antibodies and the antibody of group II can be independently used to affinity purify the polypeptide as opposed to its use in the methods of Groups V, VII, VIII.

[6] The polypeptides of Group I, the antibody of Group II and the method of groups VI, X, XI are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, and they have different designs, modes of operation, and effects. (MPEP § 802.01and § 806.06). In the instant case, the polypeptide of Group I, the antibody of group II is neither made nor used by the method of Groups VI, X and XI.

[7] The polynucleotides of Group III, and the method of group VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotide can be independently used to make recombinant protein as opposed to its use in the methods of Group VI.

[8] The polynucleotides of Group III, and the methods of Groups V, VII, VIII, X, XI are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, and they have different designs, modes of operation, and effects. (MPEP § 802.01and § 806.06). In the instant case, the polynucleotides of Group III 1-86, is neither made nor used by the method of Groups V, VII, VIII, X, XI.

[9] The pharmaceutical composition comprising the binding agent of Group IX, and the methods of Groups X, XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case because the

agent binds to the polypeptide it can be used to make an affinity column to purify the polypeptide as opposed to its use in the methods of Groups X, XI.

[10] The pharmaceutical composition comprising the binding agent of Group IX, and the methods of Groups V, VI, VII, VIII, are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, and they have different designs, modes of operation, and effects. (MPEP § 802.01and § 806.06). In the instant case, the pharmaceutical composition comprising the binding agent of Group IX, is neither made nor used by the method of Groups V, VI, VII, VIII.

[11] MPEP § 803 sets forth two criteria for a proper restriction between patentably distinct inventions: (A) The inventions must be independent or distinct as claimed and (B) There must be a serious burden on the examiner. As shown above, each of the inventions of Groups I through XI are independent or distinct, thus satisfying the first criterion for a proper restriction. MPEP § 803 additionally states that a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search. Each of the inventions requires a separate patent and non-patent literature and sequence search and thus, co-examination of the inventions of Groups I-XI would impose a serious burden on the examiner.

[12] It is noted that the claims will be examined only to the extent the claims read on the elected subject matter.

[13] Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

[14] Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Notice of Possible Rejoinder

[15] The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process

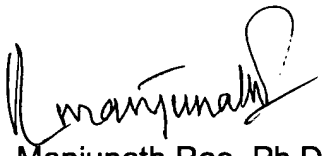
claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath Rao whose telephone number is 571-272-0939. The examiner can normally be reached on Mon to Fri, 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, P.Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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Primary Examiner
Art Unit 1656